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COVER NOTE

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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	COMMISSION STAFF WORKING DOCUMENT Subsidiarity Grid Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) and Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) and Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 and Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products

Delegations will find attached document SWD(2023) 117 final.

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EUROPEAN
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COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the documents

Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast)
and
Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast)
and
Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013
and
Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products

{COM(2023) 221 final} - {SEC(2023) 172 final} - {SWD(2023) 118 final} -
{SWD(2023) 119 final}

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

The package of four legislative proposals intended to reform the supplementary protection certificate (SPC) regime includes:

- two recast Regulations (for medicinal and plant protection products respectively) based on Article 114(1) of the Treaty on the Functioning of the EU (TFEU), which empowers the European Parliament and the Council to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States, which have as their object the establishment and functioning of the internal market, and
- two Regulations (for medicinal and plant protection products respectively) based on Article 118, first sentence, of that treaty, which empowers the European Parliament and the Council to establish measures for the creation of European intellectual property rights throughout the EU, including the setting up of centralised Union-wide authorisation, coordination and supervision arrangements.

Article 118 therefore provides an express legal base for EU-wide intellectual property rights. It is also the legal basis for Regulation (EU) 1257/2012 of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

In the case of both Article 118(1) and Article 114(1) TFEU, the Union's competence is shared.

*Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU[1]. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU[2] sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU[3] sets out the areas for which the Union has competence only to support the actions of the Member States.*

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[4]:

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

The Commission conducted a public consultation in the course of the SPC evaluation (between 12 October 2017 and 4 January 2018). In addition, the Max Planck Institute (MPI) study mentioned below included a survey among stakeholders in the EU Member States (2017), conducted by the Allensbach Institute (hereinafter 'the Allensbach survey'), which included several questions relating to the operation of the current (national) SPC regimes. Moreover, from 8 March to 5 April 2022 interested parties could provide feedback to Commission's Call for Evidence.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN
[3] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

Both the explanatory memoranda of the proposals and the common impact assessment report (chapter 3) contain a section on the principle of subsidiarity.

2.2 Do the explanatory memoranda (and impact assessment) accompanying the Commission's proposals contain an adequate justification regarding the conformity with the principle of subsidiarity?

Yes. The explanatory memoranda, which summarise Chapter 3 of the Impact assessment report, explain that 1) the two recast proposals are based on Article 114(1) TFEU which is the same legal basis already used for Regulations (EC) No 469/2009 and (EC) No 1610/96 and 2) for the two unitary SPC Regulations, only Article 118(1) TFEU can be applied for the creation of European intellectual property titles.

Despite the fact that SPCs are already harmonised by EU law, there are still cases where some Member States have granted SPCs while identical applications have been refused in others, or granted with a different scope. SPC applicants currently face diverging decisions across the EU concerning the same product at hand, while incurring costs for applying and maintaining SPCs in several Member States. National publication practices also vary across Member States, resulting in poor transparency, which can be harmful e.g. to generics makers or follow-on manufacturers. Consequently, further EU intervention is needed to address these issues and can, unlike national intervention by Member States, ensure a coherent EU-wide framework, as well as ease the total costs and burden of fees to be paid in multiple Member States.

The unitary SPC will be an autonomous regime created by EU Regulations, just as the Community design system of 2002 (and the corresponding current proposal for a regulation for EU designs) and the EUTM under Regulation (EU) 2017/1001. An EU IP right (such as a unitary SPC) can only be created by the EU, and national legislation cannot achieve this objective, as it cannot provide for unitary protection throughout the Union. Moreover, a bundle of national SPC in the enhanced cooperation area of the unitary patent would not give full continuation of the unitary effect of the unitary patent in that area.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

The identified problems to be solved by the present package initiatives have a strong cross-border (single market) dimension and the objectives pursued by the SPC initiative can therefore not be sufficiently achieved by the Member States acting alone. Despite the fact that SPCs are already harmonised by EU law, there are still cases where some Member States have granted SPCs while identical applications have been refused in others, or granted with a different scope. SPC applicants thus face diverging decisions across the EU concerning the same application at hand, while incurring costs for applying and maintaining SPCs in several Member States. The above is particularly burdensome for follow-on companies that need to monitor SPC status across many jurisdictions. National publication practices also vary across Member States. Consequently, further EU intervention is needed to address these issues and can, unlike national intervention by Member States, ensure a coherent framework, as well as ease the current burden of applications and renewal fees to be paid in several Member States. Thus, EU action is needed to set up a centralised procedure for the granting of SPCs.

Moreover, unitary SPCs, as any other unitary intellectual property rights, can only be created at EU level (in accordance with the two Regulation proposals under Art. 118 TFEU). The unitary SPC is an autonomous IP right, applying independently of any national system. Therefore, EU action is needed

for the creation of this new IP right.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The key problems that have been identified as regards this initiative are: 1. Legal uncertainty about SPC status; 2. Cumbersome monitoring of SPC status by third parties; and 3. High cost and burden of seeking and maintaining SPC protection in the EU.

These problems result from the purely national implementation of the SPC regime; i.e. they are caused by divergent national practices for application and grant of SPCs, as well as insufficient and patchy information on the SPC status in each EU country. Although common eligibility criteria are defined in the SPC Regulations, around one in four SPC applications covering the same product resulted in divergent decisions in Member States (in respect of 740 products approved between 2004 and 2014 and referring to the same basic patent). Moreover, the problems should be seen in a general context of globally competitive pharmaceutical and PPP sector with increasingly cross-border value chains.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[5] or significantly damage the interests of other Member States?

The absence of an EU level action would conflict with the core objective laid down in Article 3 of the Treaty, which is to establish an internal market and to work for the sustainable development of Europe based on balanced economic growth and price stability, and a highly competitive social market economy.

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

The required modernisation, improvement and streamlining of the existing SPC regimes, exclusively implemented at a national level, cannot be achieved by Member States but requires Union action. Not all MS may have the resources to examine all granting criteria: according to the 2018 study by the Max Planck Institute for Innovation and Competition (MPI), national patent offices (NPOs) of 15 Member States do not use the exemption from verifying all substantive criteria (CZ, DE, DK, FR, HR, HU, IE, IT, LT, LV, NL, PL, PT, SE, SK), while other Member States do.

Moreover, as regards the unitary SPC, an extension of the unitary patent by national SPCs would not be able to give rise to a continued unitary effect. A unitary right, such as a unitary SPC, cannot be created by Member States alone.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?

The current landscape of EU SPC law is characterised by a range of diverging decisions taken by national patent offices. Although common eligibility criteria are defined in the SPC Regulations, around one in four SPC applications covering the same product resulted in divergent decisions in Member States (in respect of 740 products approved between 2004 and 2014 and referring to the

[5] https://europa.eu/european-union/about-eu/eu-in-brief_en

same basic patent).

Moreover, the duration of the grant procedure may vary between MS, taking for instance 17 months in FR to 31 months in DE. Last, the ratio of rejection per Member State differs considerably: on average, five countries (CY, EE, FI, IT, LU) reject fewer than 5% of applications while 6 countries (DK, ES, MT, NL, PL, SE) reject more than 15%, providing another example of the current inconsistencies observed in the current, national SPC granting procedure.

(e) Is the problem widespread across the EU or limited to a few Member States?

As follows from the information provided for under point (d), the problems identified affect all Member States.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

No, as the proposed measures would create a new centralised procedure and a new unitary IP right at EU level. These new measures would not need to be transposed by Member States, and participation in the new procedure by national patent offices would be on a voluntary basis. Work undertaken in the course of these procedures would also need to be financially compensated by the central authority operating the new regime.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

Both the Council[6] and the European Parliament[7] have called on the Commission to fix the current inefficiencies of the SPC system. As regards Member States, the meeting of the Commission expert Group on Industrial Property Policy (GIPP) on 18 November 2022 was dedicated solely to the SPC reform.

Several Member States shared their preliminary positions regarding the policy options presented in this impact assessment in the meeting, and/or in written contributions in advance. Among the 17 Member States who took a preliminary position, a clear majority (11) supported PO5 – a unitary SPC to complement the unitary patent. Regarding the current national SPC framework, the Member States taking the floor agreed that the current SPC fragmentation is a problem. To solve this fragmentation, some called solely for guidelines (PO1), others for a centralised procedure and/or a unitary SPC. Among those recognising the need for a centralised procedure, more Member States opted for PO4, where the examination opinion is binding on national authorities (8 Member States), than for PO3, where it is not binding (5 Member States).

[6] Council of the European Union, Intellectual property policy and the revision of the industrial designs system in the Union, Council conclusions (10 November 2020), 12339/20 (https://www.consilium.europa.eu/media/46671/st-12750-2020-init.pdf)

[7] European Parliament Committee on Legal Affairs, Report on an intellectual property action plan to support the EU's recovery and resilience, 2021/2007(INI) (https://www.europarl.europa.eu/doceo/document/A-9-2021-0284_EN.html)

2.4 Based on the answers to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

The current SPC system was created by, and thus can only be changed via, EU Regulations.

(a) Are there clear benefits from EU level action?

Yes. EU-level action would enhance the integrity of the internal market by providing for a centralised, balanced and transparent SPC system in the EU and mitigate the negative consequences resulting from redundant and potentially diverging procedures that applicants face. Hence, by its nature, action at EU level is also justified to ensure the smooth functioning of the internal market for innovative medicinal products subject to marketing authorisations, and to permit the benefits of an efficient industrial property framework to be reaped in the relevant product markets, both by innovative and follow-on manufacturers.

Based on its current average coverage (20 Member States) and duration (3.5 years), SPC protection of a given product would cost around EUR 98 500 on average. In order to cover all 27 Member States for 5 years one should pay nearly EUR 192 000 in total – not including any fees that would be charged by patent attorneys or law firms. The introduction of a centralised examination procedure, and of a unitary SPC in particular, will allow for cost savings in this regard.

Currently, it is very costly and burdensome for follow-on manufacturers (e.g. generics makers) to assess the status of SPC protection for a given product throughout the EU and they may need to monitor up to 27 SPCs per each product. The information relating to this product may be dispersed across various IT systems, formats and linguistic regimes, thus making it much more cumbersome to enter the generic/biosimilar market, especially for SMEs.

Last, only an EU level action would allow a unitary patent to be extended in a unitary way, namely by the new unitary SPC.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

The proposed centralised procedure for the granting of national certificates, also able to result in the granting of a unitary certificate, on the basis of a single application that would undergo a single examination process, will clearly result in economies of scale compared to the current situation in which multiple national applications for certificates need to be filed and examined separately in each Member State where protection is sought, in respect of a given product. This current situation entails duplication of work and results in high costs, poor transparency and poor legal certainty. This impacts not only innovative firms developing products eligible for SPC protection, but also makers of follow-on products such as generic medicines. This initiative will clearly contribute to improving the functioning of the internal market in the pharmaceutical and agrochemical sectors.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

The completion of the single market in the area of will create greater legal certainty, resulting in lower costs and administrative burden for innovative firms, and in better transparency and legal certainty for third parties such as generics makers – which will indirectly benefit consumers, and

particularly patients.

The proposed centralised procedure for the granting of national and/or unitary certificates covering several Member States will make it easier and less costly for innovative firms to obtain SPC protection across the Union, including through the combined use of national and unitary certificates. This will also increase predictability, help firms reduce costs in managing multinational IP portfolios, and make it easier and cheaper for makers of follow-on products to assess SPC status across the EU. The Union-wide approach implemented by the centralised procedure will also ensure that the applicable rules and procedures are consistent across the Union, ensuring legal certainty for all relevant market participants.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

Yes. Competence in the area of SPCs will continue to be a shared one, as the existing national avenues for the granting of certificates will not be removed. The proposed completion of the single market in the area of SPCs through the introduction of a centralised procedure and the creation of unitary SPCs promises to bring about substantial economic benefit for both innovators and makers of follow-on products. National offices will also be able to participate in the new centralised examination procedure and receive remuneration for the tasks done in this capacity.

(e) Will there be improved legal clarity for those having to implement the legislation?

It is expected that the new procedure and the unitary SPC will lead to improved legal clarity, in particular compared to the current fragmentation owed to diverging decisions undertaken by national patent offices.

3. Proportionality: How the EU should act

3.1 Do the explanatory memoranda (and any impact assessment) accompanying the Commission's proposals contain an adequate justification regarding the proportionality of the proposals and a statement allowing appraisal of the compliance of the proposals with the principle of proportionality?

Yes.

As stated in the explanatory memorandum of each of the proposals, the initiative does not go beyond what is necessary to achieve the identified objectives. Its scope is limited to those aspects that Member States cannot achieve satisfactorily on their own, and where Union action can produce better results. For example, in terms of consistent decisions on SPC applications, reduction of administrative burden and costs, and improving legal certainty as well as transparency.

Moreover, the impact assessment in its section 7.4 assesses the compliance of the options with the proportionality principle. It further explains that the options considered provide a mix of Member State and EU level actions with gradual increase of the EU level intervention. Possible legal instruments for implementing policy options are in the case of PO1 a set of recommendations; and in the case of PO2-5 an amendment (or recasting) of the existing SPC regulations.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memoranda or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed action in form of the four proposals is clearly an appropriate way to achieve the objectives. It cannot be envisaged to introduce a centralised procedure or a unitary SPC in any other way.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

Yes.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

Since the current SPC regime is already governed by Regulations, no other instrument can be envisaged for this initiative.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

Yes. It is foreseen that under certain conditions the centralised procedure has to be used in order to reduce the risk for national discrepancies (e.g. as soon as certain criteria are met, such as holding a European patent and, for medicinal products, a centralised marketing authorisation), but national applications will not be abolished. Member States' national patent offices will also be able to participate in the centralised examination procedure, resulting in the granting of national SPCs and/or unitary SPCs. Moreover, as regards the granting of a national SPCs on the basis of the new centralised procedure, a MS may deviate from the binding centralised examination opinion in certain cases, and moreover the validity of such a SPC may still be challenged before a national court – i.e. a certain degree of national autonomy will be preserved.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

This proposal will have no impact on the EU budget, since the system will remain fully self-funded (by applicants' fees). The EUIPO as the new examination authority will implement the new proposal. The necessary set-up costs related to the tasks conferred to the Office, including the costs of new digital systems, will be financed from the Office's accumulated budgetary surplus.

National Offices would see a diminished workload as regards national applications and a loss in income from application fees (for a breakdown, see Annex 5F of the impact assessment), but may choose to participate in the examination procedure in exchange for remuneration. Additionally, a system of financial transfers should be set up to compensate for these losses. In light of these aspects, the financial burden created on NPOs is proportionate with the objectives to be achieved.

SPC applicants will benefit from cost reduction compared to the baseline: currently, costs are on average 98 500 EUR for 20 Member States for a duration of 3.5 years. To cover all 27 Member States for 5 years, this would cost 192 000. These numbers do not yet include agents or attorney fees. The introduction of a centralised examination procedure, and of a unitary SPC in particular, will allow for cost savings, creating a reduction in financial or administrative costs for applicants.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Given that SPCs are already harmonised by EU law, there are not special circumstances that would apply in this regard for individual Member States. While certain Member States currently make use of the exception provided for in Article 10(5) of Regulation (EC) No 469/2009, namely that not all granting criteria of Article 3 of those Regulations would need to be examined, national patent offices from those Member States may still participate in the centralised examination (albeit just one such examiner per panel).

Last, the unitary SPC will only be able to extend a unitary patent in those Member States participating in the unitary patent system (17, initially).